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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,521	02/15/2002	James Edward Brehove	0045-1	3492

7590

09/30/2003

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Morristown, NJ 07960

EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/077,521

Applicant(s)

BREHOVE, JAMES EDWARD

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-16 are included in the prosecution of this application.

#### ***Information Disclosure Statement***

The reference Caujolle et al cited in the information disclosure statement filed June 4, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a English translation or a English abstract has not been provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-5, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sor nson et al (5,972,317) in view of Hsu et al (5,874,476) in further view of Saischek t al (4,608,440).**

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Sorenson et al teach a method and composition for treating diseased nails. Sorenson teaches that the infiltration of fungal diseases result in nail disease. See column 1, lines 19-46. The nail composition includes a medicament and proteolytic enzymes to enhance penetration of the medicament in a 25:75 to 75:25 ratio. See abstract, column 3, lines 40-45, and column 4, lines 48-65. The medicament may be an antibacterial, antifungal, or antimycotic agents. See example 1. Additionally, example 1 contains boric acid in the amount of 51.4 to 61.3%. Note boric acid is a conventional antifungal agent.

Sorenson et al do not specify the instant antifungal boric acid derivatives.

Hsu et al teach inhibiting the growth of microorganisms with a dihalorformaldoxime carbamates and other conventional antimicrobials agents such as instant 1, 3, 2-dioxaborinane. See column 3, lines 6-63. The agents may be used in a variety of field such as cosmetics and toiletries.

Saischek et al teach 1, 3, 2-dioxaborinanes have outstanding fungicidal activity and algicidal activity. See column 1, lines 15-20. Saischek teaches the use of the boric acid containing compounds for a broad spectrum of harmful organisms from various fungal classes. See column 2, line 67 to column 3, lines 3. The reference teaches the use of hydrocarbons and mineral oil fractions as solvents for the agent. See column 4, lines 34-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sorenson et al and Hsu et al and utilize the instant antifungal. One would be motivated to do so since Hsu et al teach the

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conventional use of 1, 3, 2-dioxaborinane as antibacterial agents. Further, one would be motivated to utilize the instant agent among the conventional antibacterial agents provided by Hsu since Saischek et al disclose that 1, 3, 2-dioxaborinane have outstanding antifungal activities against various fungal classes. Therefore, one would be motivated to use the instant antifungal to treat fungal nail diseases since they have excellent biocidal properties and Sorenson teaches the use of boric acid.

**Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlrab et al (5,346,692) in view of Hsu et al (5,874,476) in further view of Saischek et al (4,608,440).**

Wohlrab et al teach a nail laquer for the treatment of onychomycosis. The composition includes a cellulose derivative (film former), 1-50% of an antimycotically active substance, volatile solvents, urea (penetration enhancer), and plasticizers.

Sorenson et al do not specify the instant antifungal boric acid derivatives.

Hsu et al teach inhibiting the growth of microorganisms with a dihaloformaldoxime carbamates and other conventional antimicrobials agents such as instant 1, 3, 2-dioxaborinane. See column 3, lines 6-63. The agents may be used in a variety of field such as cosmetics and toiletries.

Saischek et al teach 1, 3, 2-dioxaborinanes have outstanding fungicidal activity and algicidal activity. See column 1, lines 15-20. Saischek teaches the use of the boric acid containing compounds for a broad spectrum of harmful organisms from various fungal classes. See column 2, line 67 to column 3, lines 3. The reference teaches the

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use of hydrocarbons and mineral oil fractions as solvents for the agent. See column 4, lines 34-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wohlrab et al and Hsu et al and utilize the instant antifungal. One would be motivated to do so since Hsu et al teach the conventional use of 1, 3, 2-dioxaborinane as antibacterial agents. Further, one would be motivated to utilize the instant agent among the conventional antibacterial agents provided by Hsu since Saischek et al disclose that 1, 3, 2-dioxaborinane have outstanding antifungal activities against various fungal classes. Therefore, one would be motivated to use the instant antifungal to treat fungal nail diseases since they have excellent biocidal properties.

#### ***Miscellaneous Remarks***

The examiner points out that a significant nail formulation would be allowable.

#### ***Conclusion***

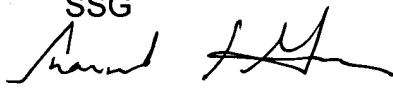
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

  
9/26/03

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600